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GENERAL ELECTRIC COMPANY (PCPI)
C/O FLETCHER YODER
P. O. BOX 692289
HOUSTON, TX 77269-2289

EXAMINER	
NGUYEN, TRAN N	

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JOHN ERIC TKACZYK, MARIA LATROU,
and NARESH KESAVAN RAO

Appeal 2009-009112
Application 10/065,159
Technology Center 3600

Before: MURRIEL E. CRAWFORD, ANTON W. FETTING and
JOSEPH A. FISCHETTI, *Administrative Patent Judges.*

CRAWFORD, *Administrative Patent Judge.*

DECISION ON APPEAL[1]

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

STATEMENT OF THE CASE

This is an appeal from the final rejection of claims 1-40. We have jurisdiction to review the case under 35 U.S.C. §§ 134 and 6 (2002).

The claimed invention is directed to network-based systems and methods for managing clinical research information (Spec. para. [0001]). Claim 1, reproduced below, is further illustrative of the claimed subject matter.

> 1. A method for managing clinical study (CS) information for a clinical research entity via a server system coupled to a centralized database and at least one client system, said method comprising:
>
> receiving at the server system CS information relating to at least one patient involved in a clinical study, the CS information being entered through a user selected template displayed on the client system, wherein the user selected template is selected from a plurality of templates stored in a centralized database, each of the plurality of templates configured to correspond to specific clinical studies;
>
> storing CS information received at the server system in the centralized database;
>
> tracking CS information stored in the centralized database;
>
> updating the centralized database periodically with newly received information to maintain CS information; and
>
> providing CS information in response to an inquiry.

The references of record relied upon by the Examiner as evidence of obviousness are:

Goldwasser	US 4,737,921	Apr. 12, 1988
Brown	US 6,196,970 B1	Mar. 06, 2001
Rice	US 2002/0042723 A1	Apr. 11, 2002

Appellants Admitted Prior Art (hereinafter "AAPA").

Claims 1-16 stand rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness; claims 1-3, 6-9, 13-14, 16-19, 22-25, 29-30, 32-33, and 36-38 stand rejected under 35 U.S.C. § 102(b) as being anticipated by

Brown; claims 4-5, 15, 20-21, 31, and 34-35 stand rejected under 35 U.S.C. § 102(b) as anticipated by Brown, or, in the alternative, under 35 U.S.C. § 103(a) as unpatentable over Brown in view of Goldwasser; claims 10-11, 26-27, and 39-40 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Brown in view of Rice; and claims 12 and 28 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Brown in view of AAPA.

We REVERSE.

ISSUES

Did the Examiner err in asserting that the term "tracking," as recited in independent claim 1, is indefinite?

Did the Examiner err in asserting that Brown anticipates "each of [a] plurality of templates configured to correspond to specific clinical studies," as recited in independent claims 1, 14, 17, 30, and 33?

FINDINGS OF FACT

Specification

The Specification discloses that CRCS utilizes a plurality of standardized templates for inputting CS data for a clinical study. CRCS enables a supervisor to manage at least one clinical study (para. [0015]).

Tracking component 66 tracks and cross-references data, including modifying existing data (para. [0028]).

In one embodiment, when a user creates a new clinical study, the user selects a create a new clinical study button within system 10. System 10 then displays a standardized template wherein all the fields within the template are available for use. Additionally, specific fields common to

many clinical studies can be selected from a drop down list, check boxes, or other manner for entering data could be used. Data is then entered by a user in other fields within the standardized template. In another embodiment, certain fields within a standardized template may be automatically filled based on the type of medical application or type of treatment being utilized to treat a patient (para. [0036]).

Brown

Brown discloses a system 100 to collect and analyze data from human subjects engaged in medical research using a protocol or other intelligent message, which acts in place of a researcher, investigator, clinician, or other medical expert (col. 4, ll. 63-67).

At a step 206 the set of research subjects 111 view some portion of the protocol 131 that was sent to the set of research subject devices 110 by looking at a presentation screen or other output element 112 contained in the research subject device 110 (col. 6, ll. 19-23).

At a step 216, the medical research expert 121 review the updated information and protocol 131 and the other information input by the set of research subjects 111 and either leave the updated research information and protocol unchanged or modify it as necessary (col. 7, ll. 1-6).

ANALYSIS

Tracking and Updating

We are persuaded that the Examiner erred in asserting that the term "tracking," as recited in independent claim 1, is indefinite (App. Br. 10-14; Reply Br. 5-6). While we agree with the Examiner that Appellants do not

provide an explicit definition for either tracking or updating, it is a canon of claim construction that two distinct claim elements should be given full effect. *See Unique Concepts, Inc. v. Brown*, 939 F.2d 1558, 1563 (Fed. Cir. 1991). When interpreted in such a light, and in view of tracking component 66 set forth in the Specification, one of ordinary skill would understand that "tracking" denotes a passive observation of data in the centralized database, while "updating" denotes actively changing the data in the centralized database. While we again agree with the Examiner that the disclosure of tracking component 66 is a bit confusing in that it performs all of tracking, cross-referencing, and modifying data (para. [0028]), the fact that tracking component 66 performs both tracking and updating functions does not conflict with the fact that the two functions are discrete.

Plurality of Templates Configured to Correspond to Specific Clinical Studies

We are persuaded that the Examiner erred in asserting that Brown anticipates "each of [a] plurality of templates configured to correspond to specific clinical studies," as recited in independent claims 1, 14, 17, 30, and 33 (App. Br. 30-32). We disagree that successive updates of the same protocol 131 correspond to a plurality of templates. Most prominently, the Examiner has not shown where Brown discloses that previous versions of protocol 131 are stored.

Moreover, even assuming *arguendo* that successive updates of the same protocol 131 correspond to a plurality of templates, and that the automatic selection of the "latest version" of protocol 131 corresponds to a "user selected template," all versions of protocol 131 are for the same

specific clinical study, and not "studies" as claimed. While we acknowledge the Examiner's point that "different, separate, and distinct clinical studies," is not explicitly recited (Exam'r's Ans. 47-48) (emphasis omitted), a combination of the context of "specific clinical studies" is set forth in Appellants' Specification (paras. [0015], [0036]) and the use of the plural "studies" in the claim requires a claim construction that the "specific clinical studies" are different, separate, and distinct.

REVERSED

hh

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